NORTH CAROLINA
ADVOCATES for JUSTICE
Protecting people's rights.

You have been told that the bill protects consumers because legal immunity does not apply if the manufacturer made false representations to the FDA during the approval process. What you have not been told is that subsection (b)(2) is carefully drafted to limit the "fraud exception" to cases in which the FDA made a formal determination "by final agency action" that the manufacturer "intentionally" made material misrepresentations. The FDA never makes such a determination. It always settles claims of misrepresentation, without a finding of fraud "by final agency action." The "fraud exception" is itself fraudulent.

Similarly, you have been told that there is "only" a "rebuttable presumption" of immunity, which can be overcome by "clear and convincing evidence." What is not explained is why multibillion dollar drug companies, who have done exceedingly well in the NC courts under the usual burden of proof, need this heightened level of protection, unavailable to other civil defendants. Nor have you been told that the bill drafters inserted a phrase in subsection (a) -- "and the manufacturer or seller is not liable" -- that has no apparent purpose other than to make the so-called "rebuttable presumption" irrebuttable.

The proponents of this bill say that it does not provide immunity. If that is true, then they should not object to five amendments:

1. In subsection (a), p. 2, lines 6-7, cut ", and the manufacturer or seller is not liable."
2. In subsection (a), p. 2, lines 7-8, change "only by clear and convincing evidence" to "by the preponderance of the evidence."
3. In subsection (b)(2), p. 2, line 15, cut "Intentionally, and".
4. In subsection (b)(2), p. 2, lines 15-16, cut "as determined by final agency action."
5. In subsection (c), p. 2, lines 23-24, cut "if the action is not based upon allegations that the product was not safe or effective or that the manufacturer failed to provide an adequate warning."

One final point. Section 2 provides that the effective date of the new statute is October 1, 2012, and that it applies to "actions commenced on or after the effective date." In other words, if someone is injured by a defective drug before the effective date, but can only file suit after October 1, 2012, this bill purports to extinguish their preexisting vested rights. That would be unconstitutional. Gardner v. Gardner, 300 N.C. 715, 718-19, 268 S.E.2d 468, 471 (1980); North Carolina Constitution, Article IV, Section 13(2).

In North Carolina, we believe in personal responsibility, and that every person and every corporation should be accountable for their actions. This bill violates those fundamental principles.

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